Section 9
BEAR® 1000 Ventilator
Preventive Maintenance Procedure

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1155340

Bear Medical Systems, Inc.

Bear Medical Systems, Inc.

1100 Bird Center Drive • Palm Springs, CA 92262
Phone: (909) 788-2460 • (800) 937-3750
Fax (760) 778-7377

50000-12142 • MARCH 1994

RECOMMENDED SERVICE PROCEDURE

Preventive Maintenance on the BEAR® 1000 Ventilator should be completed a minimum of once each year. Maintenance is intended to be done in the hospital by a Bear Medical Systems Authorized Service Technician or a Bear Medical Systems Trained Hospital Service Technician.

Ventilator Preventive Maintenance includes:

- Visually inspecting and cleaning of external surfaces, controls, attachments and accessories.
- Opening and cleaning the interior of the unit.
- Visually inspecting all tubing, electrical wiring, connectors, and crimps, screws, nuts and hardware. Checking the general condition of all other internal components or assemblies.
- Replacing the Air and O2 filters.
- Replacing the Air and O2 inlet bowls and seals.
- Replacing the ambient air intake filters.
- Pneumatic and electronic verification and calibrating if required.
- Performing the Operational Verification Procedure.

CAUTION

Before using any test equipment (Electronic or Pneumatic) for calibration procedures (other than Operational Verification), the accuracy of the instruments must be certified by a testing laboratory. The laboratory master test instruments must be traceable to the U.S. Bureau of Standards or Equivalent. When variance exist between indication and actual values, the calibration curves) provided for each instrument by the testing laboratory) must be used to establish the actual correct values. This certification should be performed at least once every six months. More frequent certification may be required based on usage and environment.

EQUIPMENT REQUIRED

In addition to the equipment and supplies specified in the Calibration Section of this manual, the following will be required to perform the preventive maintenance:
50000-13001 PM Kit containing the following parts:

Gas Inlet Filters (2 each) 52000-01145
Bowl Kit (2 each w/ seals) 52000-01144
Ambient Air Filter (2 each) 51000-08655

BIO-TEK Digital Safety Analyzer Model 170 or equivalent.

EXTERIOR INSPECTION

1. Turn off the ventilator and disconnect from AC power and pressurized gas at the wall sources.

CAUTION

Do not use Methyl Ethyl Ketone (MEK) or Trticloroethylene, as Damage to surfaces will result. Do not allow any liquid to spill or drip into the Ventilator.

2. Clean the exterior of the unit with water or a solution of 70% Isopropyl Alcohol solution only. Wipe all surfaces with a soft cloth or disposable wipe moistened in the cleaning solution.
3. Inspect the exterior surfaces of the ventilator for broken or loose knobs. Check the display panel for scratches, cracks and alignment of LED indicators. Check all front and rear panel fittings, circuit breakers and accessories for security. Check the AC electrical cord and plug for damage. Record the reading of the hour meter on the maintenance check list.
4. Replace the ambient air intake filters at the rear of the ventilator.
5. Remove the bowl from the Air Water Trap (Figure 9-1).

WARNING

When replacing air/02 inlet filters, mark and remove one and only one fitting at a time. Replace the filter and return the fitting to its original location before removing the second fitting. Failure to follow this procedure may result in injury, including death, to the patient.

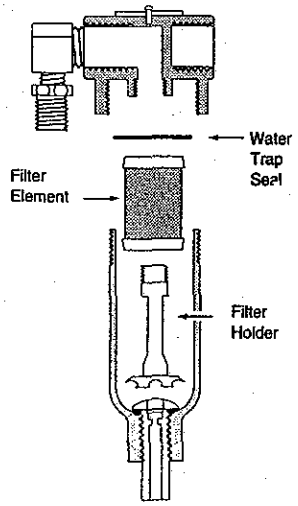

Figure 9-1
Water Trap

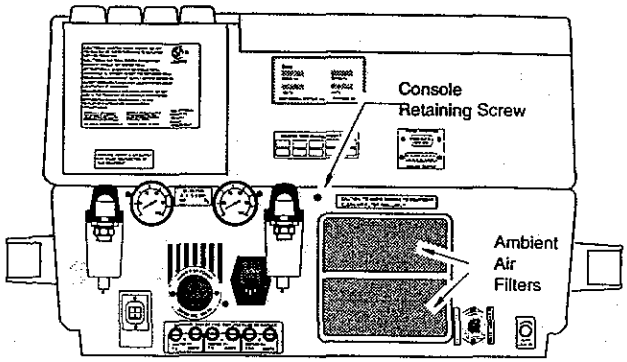

Figure 9-2
Ventilator Rear View

6. Remove the seal from the Water Trap housing using a small pocket screwdriver and discard.

7. Install the new seal from the kit.

8. Turn the filter holder counterclockwise and remove from housing. Discard old filter element (Figure 9-1).

9. Install the new filter element as illustrated on the Water Trap housing and tighten.

10. Install new bowl on the housing of the water Trap.

11. Repeat the procedure for the Oxygen water trap.

CAUTION

The circuit boards are subject to damage by static electricity. Do not touch components, circuit, or connector fingers with hands. Handle only by edges.

INTERIOR INSPECTION

1. Open the Ventilator by removing the console retaining screw (Figure 9-2).
2. Vacuum all surfaces inside the ventilator. Be sure to reach areas around connectors, circuits boards and pneumatic assemblies.
3. Visually inspect for any overheated components, loose connectors, damaged wires or tubing, kinked tubing, loose ribbon cables, loose or missing hardware, signs of water or other residue inside Tygon tubing, loose Tywraps, poor connector crimps or loose fasteners.

Specifications

Current leakage – 100µA maximum (per UL 544)
Ground resistance – 0.1 ohms at 25.0 A (per UL 544)

CALIBRATION AND VERIFICATION PROCEDURE

Verify the Power Supply Voltages per Section 7, Page 2, Error code E39.

Perform the following Calibration and / or Calibration Verification Procedures as described in the Calibration Section, Section 5 of the BEAR® 1000 Maintenance Manual.

1. Proximal Pressure Transducer Calibration
2. Differential Pressure Transducer Calibration
3 Machine Pressure Transducer Calibration
4. FCV Pressure Transducer Calibration
5. Air and 02 Transducer Calibration
6. D/A Converter Calibration
7. Exhalation Valve Regulator Calibration
8. Inlet Check Valves and Air/ 02 Calibration
9. Nebulizer Calibration

GROUND RESISTANCE TEST

Perform a ground resistance check (always follow manufacturer's instructions for test equipment operation).

1. Connect a properly functioning leakage and grounding tester between the ground connection and the hospital grade AC plug (middle lug) and the chassis of the ventilator (any unpainted exposed metal part).

2. With the tester connected and operating, there *should be no more than 0.10 ohms resistance* between the plug ground connector, and the ventilator chassis ground.

CURRENT LEAKAGE TEST

Perform a current leakage test (always follow manufacturer's instructions for test equipment operation).

1. Connect the ventilator to a properly functioning current leakage tester.

2. Turn Mode switch to CPAP and tester on.

3. Current leakage should be less than 100 microamps, grounded and ungrounded.

OPERATIONAL VERIFICATION PROCEDURE

Perform the Operational Verification Procedure (OVP), Section 3, after the Preventive Maintenance Procedure has been performed to assure that the ventilator is functioning properly. Complete an Operational Verification Procedure Checklist form and attach it to the PM Checklist form. See the OVP for specific instructions.

BEAR® 1000 VENTILATOR
PREVENTIVE MAINTENANCE CHECK LIST

BEAR® 1000 Serial Number_____ Hour meter reading_____ Today's date _____

Service Location	_____	Service organization	_____
Address	_____	Address	_____
City, State, Zip	_____	City, State, Zip	_____
Contact	_____	Service Person	_____
Phone (___)	_____	Phone (___)	_____

VERIFICATION STEPS

STEP	PASS	FAIL	STEP	PASS	FAIL
Dust Filter	❑	❑	Air & O2 Transducers Calibration	❑	❑
Air and O_2 Inlet Filters	❑	❑	D/A Converter Calibration	❑	❑
Interior Inspection	❑	❑	Exhalation Valve Regulator Calibration	❑	❑
Vacuum Interior	❑	❑	Inlet Check Valves & Air / O2 Calibration	❑	❑
Power Supply Verification	❑	❑	Nebulizer Calibration	❑	❑
Proximal Pressure Transducer Calibration	❑	❑	Ground Resistance	❑	❑
Differential Pressure Transducer Calibration	❑	❑	Current leakage	❑	❑
Machine Pressure Transducer Calibration	❑	❑	Perform OVP	❑	❑
FCV Pressure Transducer Calibration	❑	❑			

WARNING

Do not release the ventilator for use if it does not pass all of the procedures specified in the checklist. To do so could result in personal injury including death or property damage. Refer the ventilator to a Bear Medical Service Technician or a Bear Medical Systems trained service technician for appropriate repair and/or calibration.

Signature_____

BEAR 1000 VENTILATOR
OPERATIONAL VERIFICATION ADDENDUM

Bear 1000 Serial Number_____ Hour Meter Reading_____ Today's Date _____

FLOW TRIGGER VERIFICATION

1. Set the ventilator as shown in Table 4, except set the MODE to Assist Control.
2. Set the Base Flow and Flow Trigger as specified in Table 4.
3. Slowly expand the Test Lung. Note that Proximal Airway Pressure as shown on the Proximal Pressure Gauge shows minimum negative deflection, (less than 1cm H_20), indicating that flow is entering the Test Lung.
4. Observe that an Assisted Breath is triggered. Verify operation at all settings indicated in Table 4.

TABLE 4 - FLOW TRIGGER SETTINGS

BASE FLOW	FLOW TRIGGER	PASS	FAIL
5 LPM	2.0 LPM	☐	☐
10 LPM	2.0 LPM	☐	☐
10 LPM	5.0 LPM	☐	☐
20 LPM	10.0 LPM	☐	☐

SIGNATURE: _____

CAB-17

RADIO FREQUENCY/ELECTROMAGNETIC INTERFERENCE

Following an established program when questions regarding design and function of a Bear Medical product need answers, we will make a Clinical Application Bulletin available. We hope these bulletins will clarify areas of possible confusion and increase the clinician's knowledge and understanding of the product.

QUESTION:

Is it true, transmitting with a Walkie Talkie or Cellular Phone can affect the operation of Bear Medical products?

ANSWER:

Yes, When Walkie Talkies or Cellular Phones are being operated next to a product using **Microprocessors,** they can affect its operation. Bear Medical Products that may be affected are, the Bear ® 1000 Ventilator, Bear ® 5 Ventilator, Bear ® 33 Ventilator, and the Bear VH820 ® Humidifier.

QUESTION:

How far away should we be before transmitting?

ANSWER:

This depends on the power of the Walkie Talkie or Cellular Phone. The higher the wattage when transmitting, the more likely it would be to affect the product. The closer the transmitting is to the product, the more likely it would be to affect the product.

QUESTION:

What is the effect on the product's function when interference is detected?

ANSWER:

A Walkie Talkie or Cellular phone may interfere with the internal signals in the product. If the microprocessor detects interference, the product may Alarm and go into an Inoperative condition. If changes in the monitor displays or settings occur, cease use of the transmitting device. If the Bear Medical product does not self correct or reset, restart the product and reevaluate the settings and the patient.

Bear Medical
by Allied
2085 Rustin Avenue
Riverside, CA 92507-2437

CLINICAL APPLICATION BULLETIN

RADIO FREQUENCY/ELECTROMAGNETIC INTERFERENCE

QUESTION:

Do Bear Medical Products have any protection against this type of interference?

ANSWER:

We build some protection to this type of interference into the current Bear Medical products. Although there is no current standard in the USA, voluntary compliance to IEC 601-1-2 has been adopted by Bear Medical Systems Inc.

RECOMMENDATIONS:

Although the phenomena of Radio Frequency Interference with Bear Medical products can occur, it is rare. Bear Medical Systems Inc. discourages the use of Walkie Talkies or Cellular Phone devices, from being used in the immediate vicinity of a Bear Medical product.

Bear Medical
by Allied
2085 Rustin Avenue
Riverside, CA 92507-2437

Section 3
BEAR® 1000 Ventilator
Operational Verification Procedure

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Bear Medical by Allied

Bear Medical Systems, Inc.
2085 Rustin Avenue
Riverside, CA 92507-2437 USA
Phone (909) 788-2460
(800) 232-7633
FAX (909) 351-4609

For Europe, Middle East and Africa, please contact:
Bear Medical Systems AG
Zugerstrasse 74, CH-6340 Baar
Switzerland
Phone 41-42-318155
FAX 41-42-318158
TLX 865451 BMED CH

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OPERATIONAL VERIFICATION PROCEDURE

(Operator Diagnostics)

This procedure is to assist a Qualified Operator, Hospital Service Technician, or Bear Medical Systems Service Technician ensure that the BEAR® 1000 Ventilator is in proper operating condition. A checklist is included and should be completed during each operational verification. A copy of the checklist should be maintained in the hospital file. The attached checklist may be copied, providing forms for future use.

VERIFICATION PROGRAM

The Operational Verification Procedure (OVP) is divided into two parts.

Part 1 consists of an automated series of built-in diagnostics tests and should be performed at least monthly.

Part 2 consists of additional manual verifications and should be performed at least twice a year.

Do not use the ventilator unless it passes the Operational Verification Procedure. For servicing, contact a Bear Medical Systems Service Technician or a Bear Medical Systems Trained Hospital Technician.

OPERATIONAL VERIFICATION PROCEDURE

The following verification procedure should be performed in the hospital by a Qualified Operator, Hospital Service Technician, or a Bear Medical Systems Service Technician. Familiarity with the function, set-up and operation of the BEAR® 1000 Ventilator is assumed. (*See BEAR® 1000 Ventilator Instruction Manual.*) Perform all tests in the following sequence.

WARNING

The Operator Diagnostics must never be performed when the ventilator is connected to a patient. To do so could result in serious injury to the patient.

NOTE

The use of test equipment not specified will introduce variables which may influence test results. Do not assume that a failure has occurred if the specified test equipment or its equivalent is not used.

TEST EQUIPMENT SPECIFIED FOR THE OVP

Tube, Circle 72" x 3/4 (2 ea.) 51000-02759*
Patient Wye 51000-01104*
Chamber, VH-820.....51000-02739*
Filter, Proximal Line.....50000-01106*
Filter, Mainflow 51000-01054*
Tubing, PVC, 1/4" ID, 72"
Plug for Patient Wye
Plug for Humidifier Water Port
Oxygen Analyzer, 1% Accuracy
Pressure Gauge, 0–100 psi ±1% F/S or better—Ametek Model 1903, Ashcroft type 1279, or equivalent
Pressure Gauge, 0–10 cmH_2O ±1% F/S—Marshalltown Model 86F, with scale in cmH_2O, Wallace & Tierman Model FA 14170 or equivalent
Timeter RT-200 or equivalent
Test Lung, R5, C10
Regulated Air/O_2 Source
Shut Off Valves
Stopwatch

***(or equivalent)**

WARNING

The following warnings must be read and understood before performing the procedures *described in this section.*

Under no circumstances should this medical device be operated in the presence of flammable anesthetics or other volatile materials due to a possible explosion hazard.

Liquid spilled or dripped into the unit may cause damage to the unit or result in an electrical shock hazard.

Oxygen vigorously accelerates combustion. To avoid violent ignition, do not use any gauges, valves, or other equipment that has been exposed to oil or grease contamination.

Do not release this medical device if any alarm/alert function is inoperative. To do so could result in a malfunction without warning, possibly resulting in personal injury up to including death or property damage. Refer the unit to a Bear Medical Systems Authorized Service Technician or a Bear Medical Systems Trained Hospital Service Technician.

WARNING

All tubing and fittings used to connect high pressure gas (air and oxygen) from the source to the test equipment and from the test equipment to the device being tested must be capable of withstanding a minimum supply pressure of 100 psi (7.03 kg/cm²). The use of tubing and fittings not capable of withstanding this pressure could cause the tubing to rupture, resulting in personal injury or property damage.

When verifying the operation of this medical device, do not breathe directly from the machine. Always use a fresh bacterial filter and test circuit. A hazard to the health of the service person may result.

If any of the following procedures cannot be verified as outlined in this document, do not use this device on a patient and refer it to Bear Medical Systems or a Bear Medical Systems Authorized Service Facility or a Bear Medical Systems Trained Hospital Service Technician.

CAUTION

The following cautions must be read and understood before performing the procedures described in this section.

Do not use MEK or Trichloroethylene, as damage to surface may result. Do not allow any liquid to spill or drip into the ventilator.

Do not gas sterilize the ventilator. The internal materials are not compatible with gas sterilization techniques.

Before using any test equipment [electronic or pneumatic] for calibration procedures [other than operational verification], the accuracy of the instruments must be verified by a testing laboratory. The laboratory master test instruments must be traceable to the NIST (National Institute of Standards Technology) or equivalent. When variances exist between the indicated and actual values, the calibration curves [provided for each instrument by the testing laboratory] must be used to establish the actual correct values. This certification procedure should be performed at least once every six months. More frequent certification may be required based on usage and environment.

EXTERIOR INSPECTION AND CLEANING

Inspect all cords, connectors, and fittings. Inspect the case for any cracks or other damage.

CLEANING

1. Before any cleaning of the ventilator, disconnect WALL A.C.
2. Clean the exterior of the ventilator with an appropriate bactericidal or germicidal agent. Care should be exercised not to allow any liquid to penetrate the inside of the ventilator.

CAUTION

Do not gas sterilize or steam autoclave the ventilator.

FILTERS

The cabinet air inlet filters are easily accessible for removal and cleaning. The filters may be vacuumed or washed in warm soapy water, rinsed, and thoroughly dried.

CAUTION

Do not operate the ventilator without the filters in

PLUGS AND CABLES

Plugs and cables may be wiped down with an appropriate bactericidal or germicidal agent.

PART 1

Automated Built-In Diagnostics

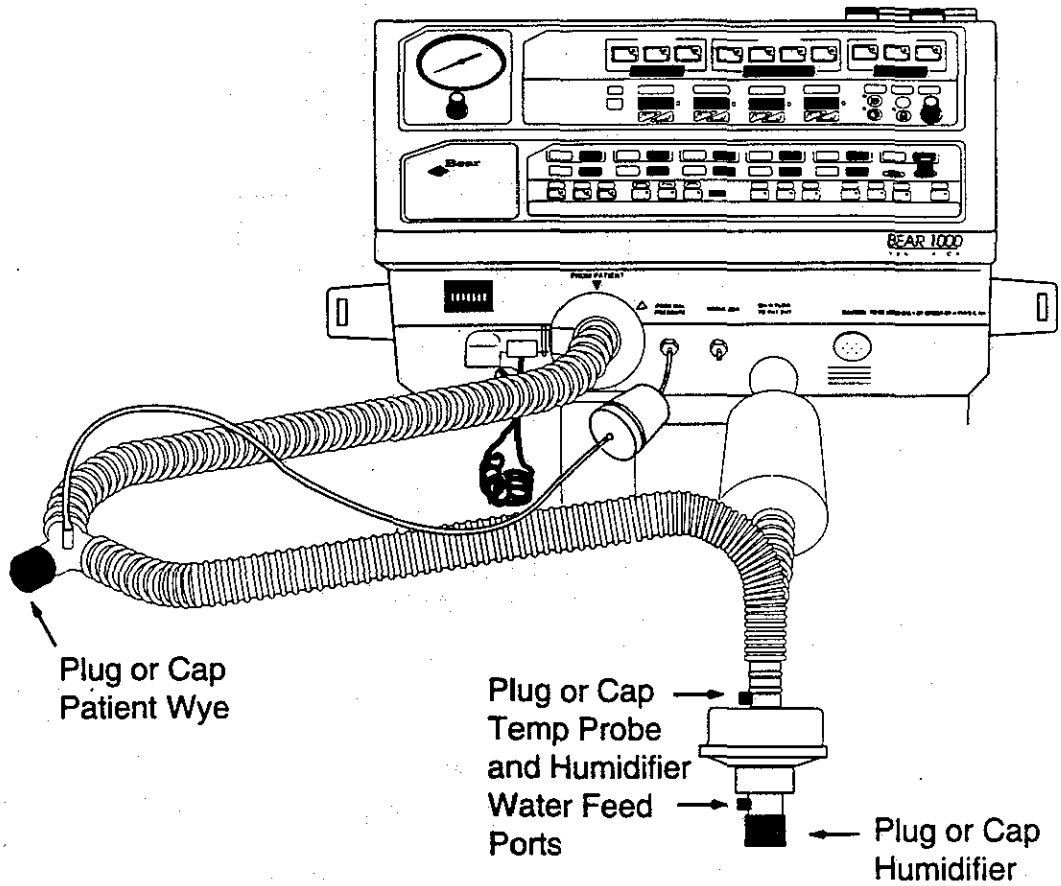

Figure 3-1
Patient Circuit Connection

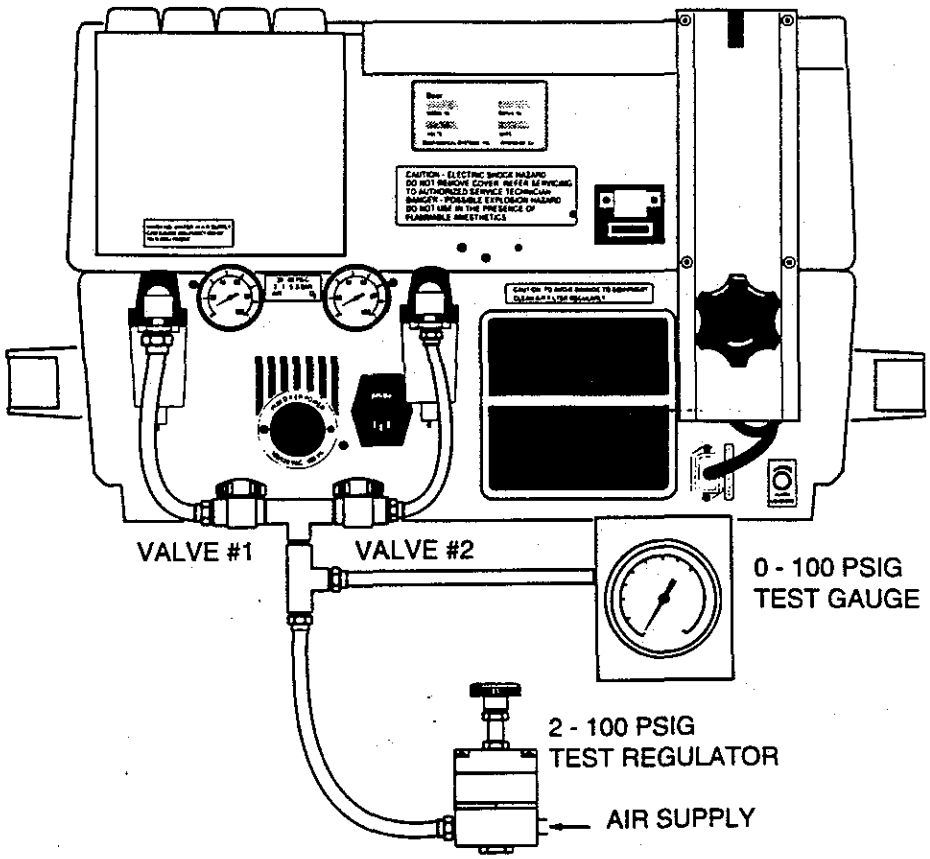

Figure 3-2
External Gas Source Connections

TEST SETUP

1. Connect the test circuits to the ventilator as shown in Figures 3-1 and 3-2.
2. Plug the open end of the patient wye and the water inlet port of the humidifier.
3. Record the reading from the Hourmeter on the checklist.

NOTE

While the Operator Diagnostics are in operation, there will be other information displayed in the displays. These are not part of the Operator Diagnostics. For an explanation of these values, see Appendix A.

NOTE

The keyboard is redefined in Diagnostics. See Figure 3-9 for these functions.

NOTE

Turn the Graphics Display OFF when running the Diagnostic tests. If the Graphics Display is on, false d2 failures may occur.

ENTERING THE OPERATOR DIAGNOSTIC MODE

NOTE

PEEP must be turned off completely prior to entering the Diagnostic Mode to avoid test failure. Be sure the PEEP control is set completely counter clockwise.

1. With the ventilator power off, depress and hold the TEST Key.
2. Turn on the ventilator power and hold the TEST Key down until the Power On Testing is complete (approx. 20 seconds).
3. While the Power On tests are running, observe that all digital displays and LEDs light.
4. When the Power On Test is complete, observe and record the Configuration Code shown in two of the displays in the Controls section (See Figure 3-9). Verify that the displayed Code matches the Configuration Code on the rear of the ventilator.

5. Verify that the pressure reading in the "PROXIMAL TRANSDUCER"window (see Figure 3-9) is 0.0 cmH20 ± 1.5 cmH20. If greater than ± 1.5 cmH20, recalibrate the transducer to zero.

WARNING

If Proximal Pressure Transducer reads >3.0 cmH20, Backup Pressure Alarm will be disabled which may result in injury or death in the event of a Proximal Line Disconnect.

6. Select one of the following tests by pressing the Test Number Key and rotating the SET knob. The selection will appear in the Test Number display window.

   a. All — All Diagnostic Tests (d 1 through d 7)

   b. d 1 — Power Up Diagnostics
   µ Processor Self Check
   ROM Check Sum
   RAM Test

   c. d 2 — Flow Control Valve Test

   d. d 3 — Blender Control Valve Test

   e. d 4 — Leak Test

   f. d 5 — Flow Delivery/
   External Flow Testing

   g. d 6 — SOPR System Test

   h. d 7 — Pressure Delivery/
   Pressure Sensing Test

7. The tests may be run in three different ways by pressing the following keys:

   a. Run Test Once
   Runs the selected test one time.

   b. Cycle Test
   Runs the selected test until it is cancelled or a failure occurs.

   c. Cancel Test

   Halts the running of diagnostics at the end of the current test.

NOTE

Due to the extensive nature of the RAM test, Diagnostic d1 takes approximately 80 seconds to complete.

NOTE

While a test is in progress, characters will be seen rapidly flashing in the Test Results display window indicating the test is in progress.

8. When a test has been successfully completed, a "P" will appear in the Test Results window.

9. If a test fails, an "F" will appear in the Test Results window.

10. Turn off ventilator to exit Diagnostic mode.

PART 2
MANUAL TESTING

Table 1—Standard Settings

PEEP Pressure	0 cmH_2O
Alarm Settings	
* I:E Override	ON
High Total Minute Volume	80 L
Low Total Minute Volume	0.0 L
High Total Breath Rate	155 BPM
Low Total Breath Rate	3 BPM
High Peak Insp Pressure	120 cmH_2O
Low Peak Insp Pressure	3 cmH_2O
* High Baseline Pressure	55 cmH_2O
* Low Baseline Pressure	0 cmH_2O
Control Settings	
Tidal Volume	0.5 L
Breath Rate	10 BPM
Peak Flow	65 LPM
% Oxygen	21 %
Pres Sup/Insp Pres	0 cmH_2O
Assist Sensitivity	5.0 cmH_2O
* Inspiratory Pause	0.0 sec
* MMV Level	0 LPM
* Compliance Comp	0.0 mL/cmH_2O
* Inspiratory Time	1.0 sec
* Pressure Slope	0
Mode	SIMV/CPAP
Waveform	Square
* 100% Oxygen	Off
* Sighs	Off
* Pressure Augment	Off
Nebulizer	Off

* Not applicable for Bear® 1000 Basic Unit.

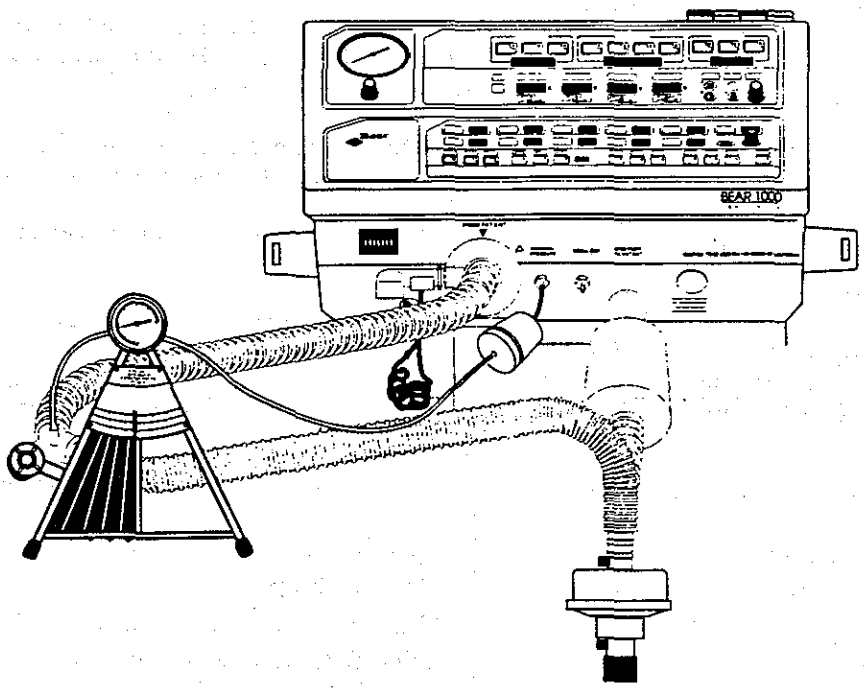

Figure 3-3

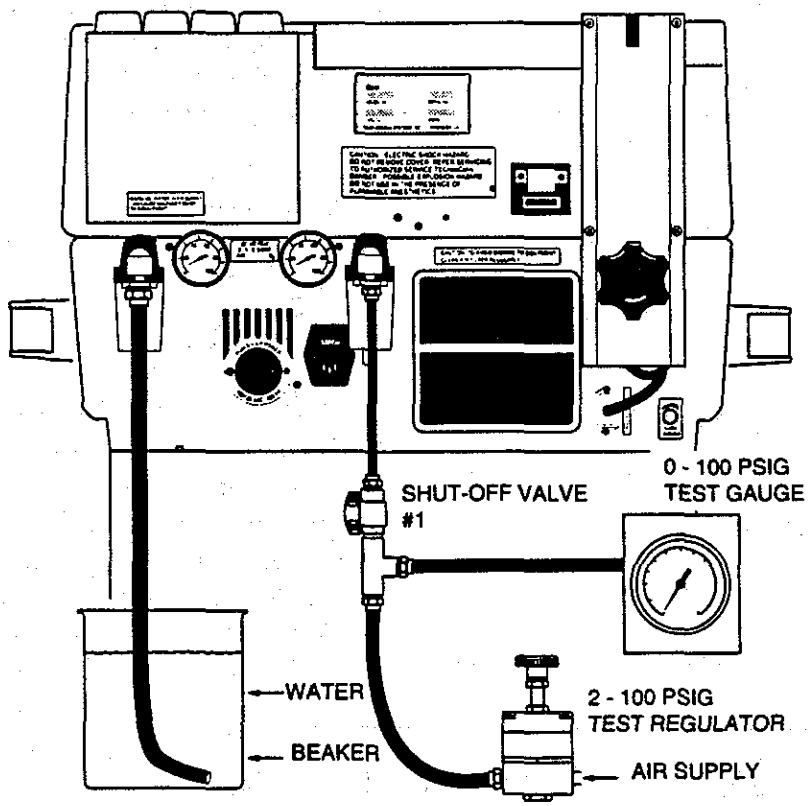

Figure 3-4

AIR/O_2 INLET CHECK VALVE VERIFICATION

1. Connect the ventilator as shown in Figure 3-3.
2. Adjust the controls as shown in Table 1 except change the Oxygen % to 60%.
3. Connect the ventilator as shown in Figure 3-4.
4. Close Valve No.1.
5. Adjust the 100 psi regulator for an indication of approximately 50 psi on the test gauge.
6. Turn ON the ventilator power, ignore any alarms.
7. Open valve No.1.
8. Verify that there is no release of bubbles from hose submerged in beaker of water.
9. Close Valve No.1 and connect the test gauge, regulator and shut-off valve to the air inlet. Connect the hose and beaker to 02 inlet. Repeat Steps 7 and 8.
10. Turn the regulator down to zero and close Valve No.1.
11. Turn the ventilator power OFF, and repeat the procedure with the power turned OFF.
12. Check the appropriate block on the OVP checklist.

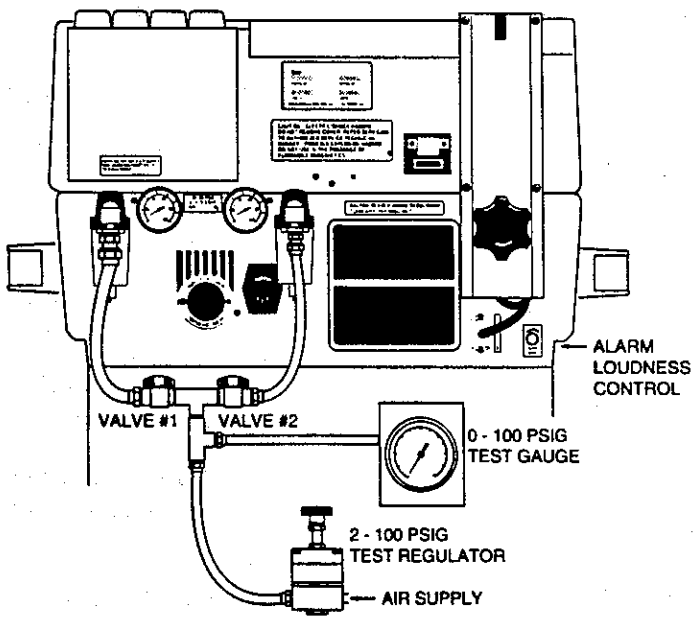

Figure 3-5

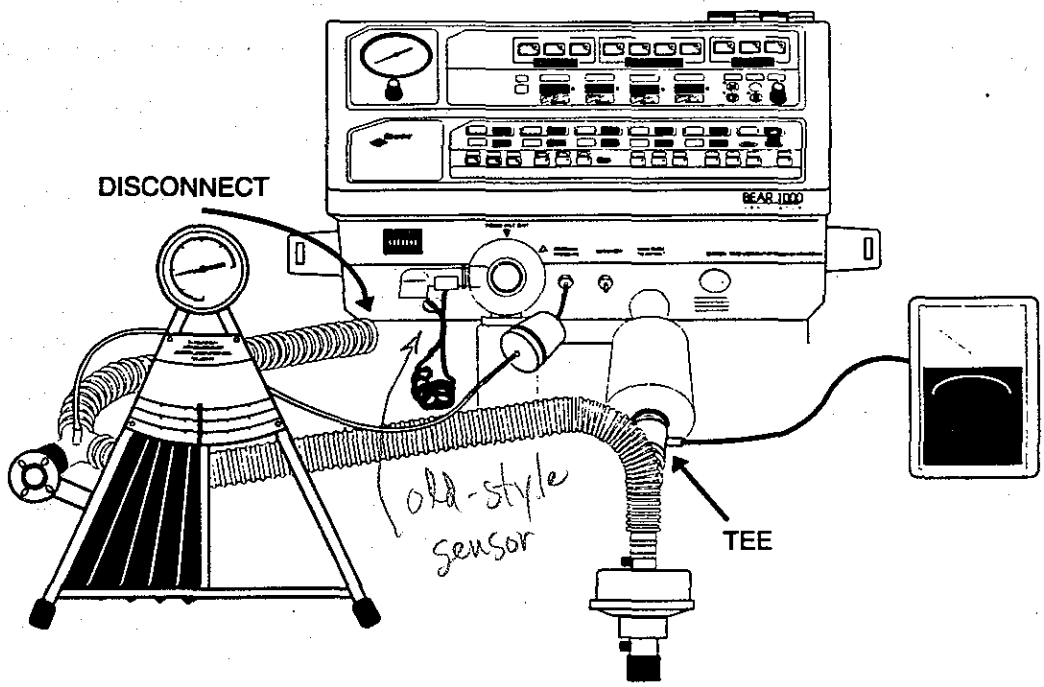

Figure 3-6

AIR/O_2 INLET PRESSURE GAUGE VERIFICATION

1. Connect the ventilator as shown in Figure 3-5.
2. Sequentially apply 10, 30, and 50 psig.
3. Verify that at each pressure the inlet gauges indicate ±5 psig of the applied pressure.
4. Change Oxygen % to 21%.
5. Close valve #2.
6. Verify that the Gas Supply failure alarm doesn't come on.

ALARM LOUDNESS TESTING

1. Set the ventilator as shown in Table 1.
2. Create any condition that will cause a ventilator alarm (i.e. Pressure limit).
3. While the alarm is sounding, adjust the alarm loudness control on the rear of the ventilator.
4. Verify that the alarm loudness can be varied but not turned completely off.
5. Reset alarm to original setting or new setting if desired.

BREATH RATE VERIFICATION

1. Set the ventilator as shown in Table 1.
2. Allow the ventilator to cycle and using a stopwatch, verify the following rates ±2 BPM:

   a. 6 BPM
   b. 60 BPM

OXYGEN BLENDING VERIFICATION

1. Refer to Figure 3-2; close valve 2 and disconnect the hose.
2. Connect an O_2 supply and apply pressure.
3. Set the ventilator as shown in Table 1, but set the breath rate at 25 BPM.
4. Connect an oxygen analyzer in line with the patient circuit as shown in Figure 3-6.
5. Vary the ventilator settings as shown in Table 2 and verify that the results agree with the specifications.

NOTE

Due to a 3.5 liter accumulator chamber within the ventilator, oxygen percentage changes will not be immediate. Allow time for stabilization to occur before verifying specifications.

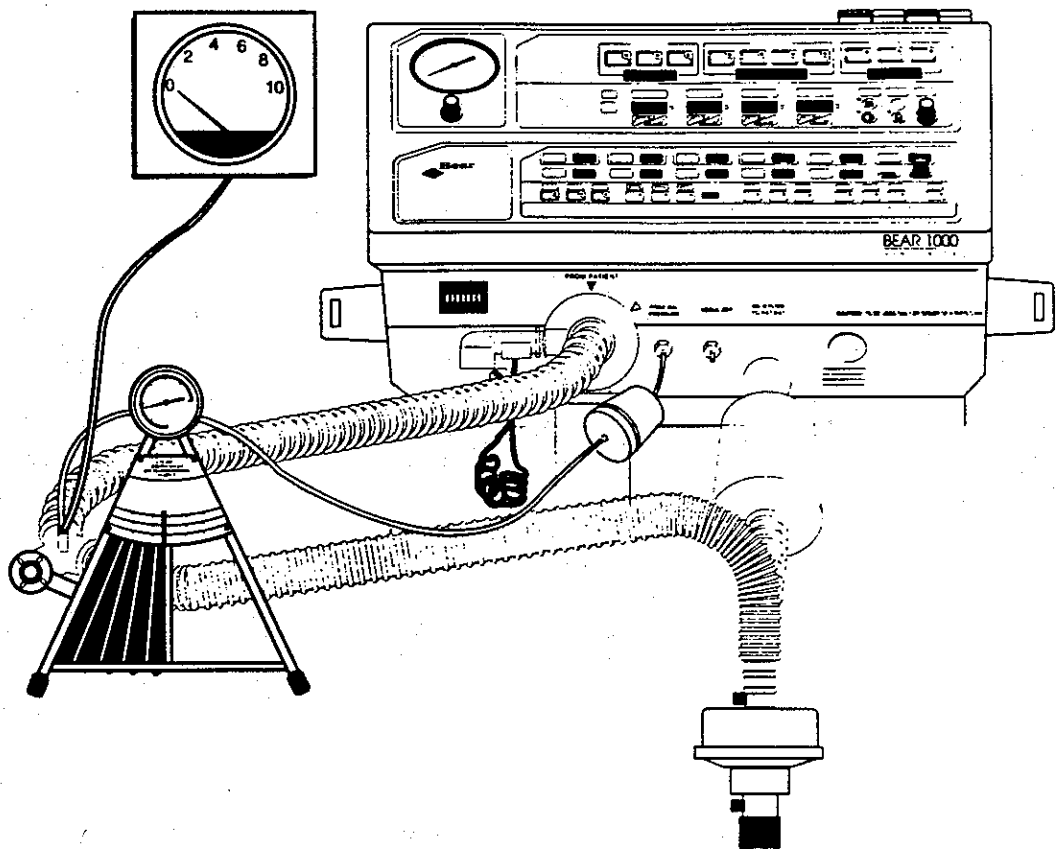

Figure 3-7

6. Disconnect the oxygen source and reconnect the air source.
7. Return the ventilator to the settings shown in Table 1.

Table 2—Oxygen Blending Settings

O_2 %	Tidal Volume	Breath Rate	Peak Flow	Specification
21%	0.50L	25	30	20 to 25%
40%	0.10	50	30	36 to 44%
40%	0.50	25	30	36 to 44%
60%	0.10	50	30	56 to 64%
60%	0.50	25	100	56 to 64%
80%	0.10	50	30	76 to 84%
80%	0.50	25	30	76 to 84%
100%	0.50	25	30	96 to 100%

ASSIST SENSITIVITY VERIFICATION

1. Set the ventilator as shown in Table 1, except set the Rate to 0 BPM
2. Connect the ventilator as shown in Figure 3-7, with the gauge configured to measure negative pressure.
3. Compress the test lung bellows and release while observing the test gauge.
4. Verify that the unit is triggered when the test gauge is deflected to a reading of 5 cmH_2O
5. Set the Assist Sensitivity to 1 cmH_2O
6. Compress the test lung bellows and release.
7. Verify that the unit is triggered when the test gauge is deflected to a reading of 1cmH_2O.

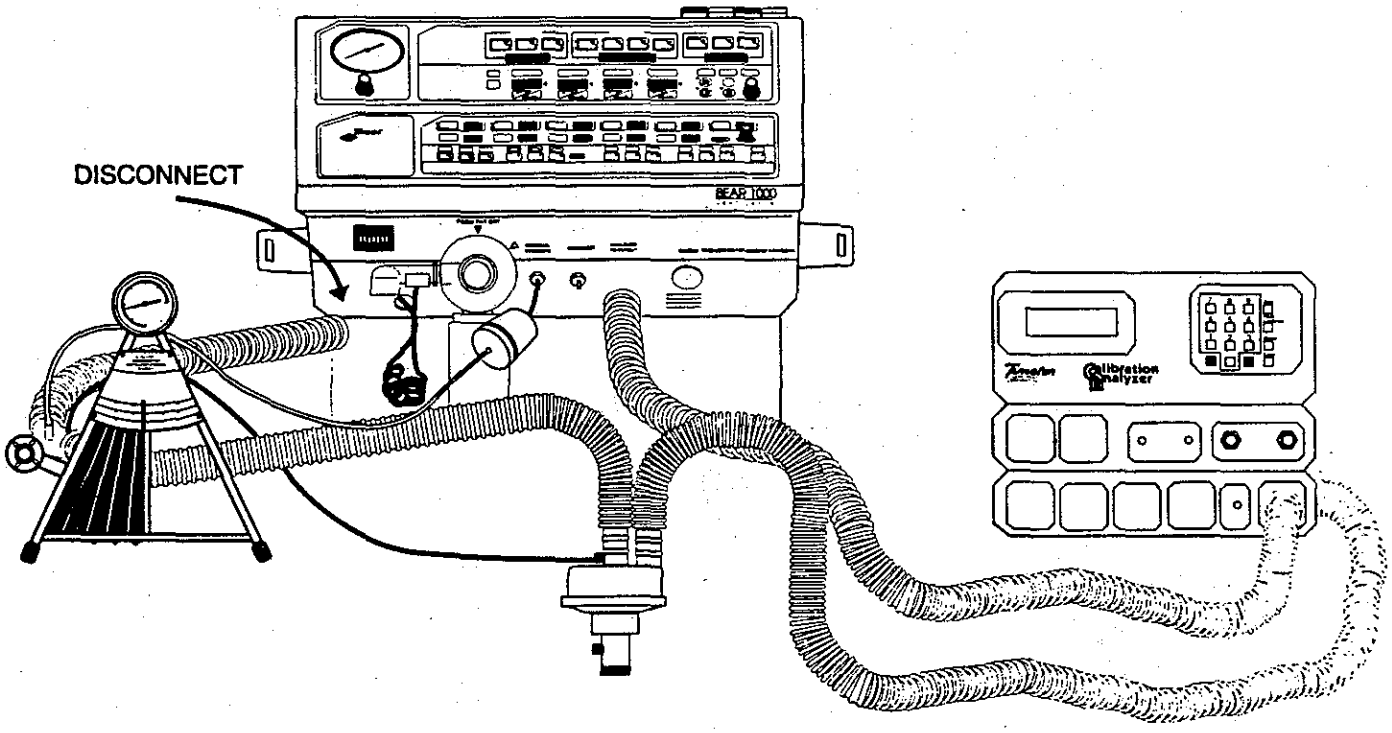

Figure 3-8

8. Repeat the preceding test to assure that the ventilator is operating properly.

DELIVERED/EXHALED VOLUME VERIFICATION

NOTE

Volume tolerances reflect values without heating or humidification

1. Connect the ventilator and analyzer as shown in Figure 3-8.

CAUTION

Do not totally occlude the Proximal Airway tube. Doing so may result in Proximal Airway gauge damage.

2. Partially occlude the Proximal Airway tube so that approximately 10 cmH2O is shown on the Proximal Airway gauge.
3. Set the ventilator as shown in Table 1 and vary the Tidal Volumes as shown in Table 3.
4. Verify that the Delivered Volumes are within the specified tolerances.

5. Reconnect expiratory limb and verify that exhaled volume readings at 0.10 and 0.50 liters are within a +0 % to -15% or +0.00 to -0.03 Liter (whichever is greater) tolerance range of the delivered volumes measured in step 3.

Table 3—Tidal Volume Settings

Tidal Volume Setting	Delivered Volume Tolerance
0.10	0.08 to .120 L
0.50	0.45 to 0.55
1.00	0.90 to 1.10
1.50	1.35 to 1.65
2.00	1.80 to 2.20

POWER LOSS ALARM VERIFICATION

1. Set the ventilator as shown in Table 1.
2. Disconnect AC power at the rear of the ventilator.
3. Verify that the Power Loss alarm sounds.

APPENDIX A

While the Operator Diagnostics are running, other parameters are displayed in the displays. The following is an explanation of these values. Refer to Figure 3-9.

Monitor Fields

DELIV FLOW

Shows the Delivered Flow in the range of 0 to 278 LPM.

EXT FLOW TRANSDUCER

Shows the Exhaled Flow in the range of 0 to 300 LPM.

GAS TEMP

Shows the Gas Temperature as measured at the Flow Control Valve in the range of 50 to 104 degrees F.

PROXIMAL TRANSDUCER

Shows the pressure seen by the Proximal Pressure Transducer in the range of -60 to 140 cmH_2O.

DELTA TRANSDUCER

Shows the pressure seen by the DELTA (differential) Pressure Transducer in the range of -140 to 60 cmH_2O.

MACHINE TRANSDUCER

Shows the pressure seen by the Machine Pressure Transducer in the range of 0 to 160 cmH_2O.

FCV PRESSURE TRANSDUCER

Shows the Flow Control Valve Pressure Transducer output in the range of 0 to 20 psig.

NOTE

The next displays uses each character as a separate indicator and reads from left to right. Each character displays either a 1 (active) or a 0 (inactive) state.

FCV/FAN

Character one will indicate that the Flow Control Valve is at its high end stop (maximum flow).

Character two will indicate that the Flow Control Valve is at its low end stop (zero flow).

Character three will indicate that the Cooling Fan within the ventilator is producing an operating signal.

AIR & O_2 SWITCH

Character one is not used at this time and the position will be blank.

Character two indicates that the Air Inlet Pressure Transducer is sensing sufficient inlet pressure.

Character three indicates that the Oxygen Inlet Pressure Transducer is sensing sufficient inlet pressure.

BLENDER/FLOW TRANSDUCER

Character one indicates that the Blending Control Valve is at its High Stop (100% oxygen).

Character two indicates that the Blending Control Valve is at its Low Stop (21% oxygen).

Character three indicates that the Flow Transducer is drawing an nominal amount of current (neither open/disconnected or shorted).

SOFTWARE REVISION

Shows software revision.

FCV/BLENDER COUNT

Counts from 0 to 120 as Flow Valve moves.
Counts from 0 to 124 as Blender moves.

FCV/BLENDER COUNT

Counts from 0 to 120 as Flow Valve moves.
Counts from 0 to 124 as Blender moves.

Control Fields

BAROMETRIC PRESSURE SET

Displays the current barometric pressure setting in the range of 10.5 to 14.7 psig. When this field is selected the value may be adjusted in increments of 0.1 by rotating the Set Knob.

Converting Altitude to Avg. Barometric Pressure

Feet	Meters	Barometric Pressure (psia)
0	0	14.7
500	152	14.4
1000	305	14.2
1500	457	13.9
2000	610	13.7
2500	762	13.4
3000	914	13.2
3500	1067	12.9
4000	1219	12.7
5000	1524	12.2
6000	1829	11.8
7000	2133	11.4
8000	2438	11.0
9000	2743	10.5

BAUD RATE SET

Displays the four RS-232 Baud rates

available as follows:

1.2	=	1200 Baud
2.4	=	2400 Baud
9.6	=	9600 Baud
19.2	=	19200 Baud

When this field is selected, the user may select one of the other three rates using the Set knob.

BEAR® 1000 VENTILATOR
OPERATIONAL VERIFICATION CHECK LIST

This checklist is for use during the BEAR® 1000 Operational Verification

BEAR® 1000 Serial Number_____ Hour meter reading_____ Today's date _____

Configuration Code _____

Service Location	_____	Service organization	_____
Address	_____	Address	_____
City, State, Zip	_____	City, State, Zip	_____
Contact	_____	Service Person	_____
Phone (___)	_____	Phone (___)	_____

VERIFICATION STEPS

STEP	PASS	FAIL	STEP	PASS	FAIL
Inspection and cleaning performed	❑	❑	Pressure Delivery/Pressure Sensing Test (d7)	❑	❑
Display Panel Verification	❑	❑	Air and O_2 Check Valves	❑	❑
Power Up Diagnostics (d1)	❑	❑	Air and O_2 Inlet Pressure Gauges	❑	❑
Proximal Transducer Verification	❑	❑	Alarm Loudness Test	❑	❑
Flow Control Valve Test (d2)	❑	❑	Breath Rate Verification	❑	❑
Blender Control Valve Test (d3)	❑	❑	Oxygen Blending Verification	❑	❑
Leak Test (d4)	❑	❑	Assist Sensitivity Verification	❑	❑
Flow Delivery/External Flow Test (d5)	❑	❑	Delivered/Monitored Volume Verification	❑	❑
SOPR System Test (d6)	❑	❑	Power Loss Test	❑	❑

WARNING

Do not release the ventilator for use if it does not pass all of the verification procedures specified in the checklist. To do so could result in personal injury including death or property damage. Refer the ventilator to a Bear Medical Service Technician or a Bear Medical Systems trained service technician for appropriate repair and/or calibration.

Signature_____

PROCEDURE COMPLETE

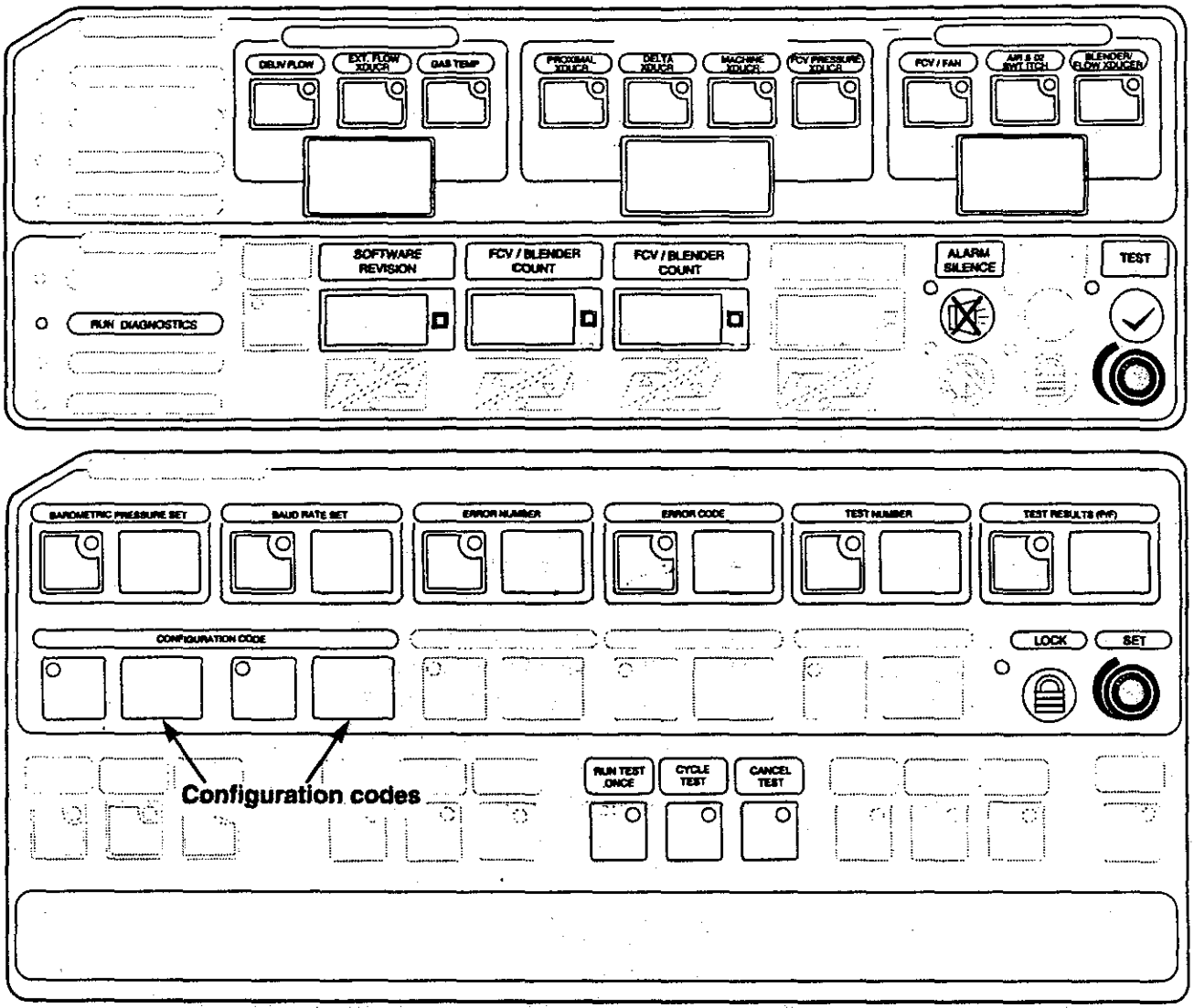

FIGURE 3-9

Active Functions and Displays for Operator Diagnostics

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
Nebulizer will not deliver flow.	Nebulizer not delivering aerosolized medication.	1. NEBULIZER key turned off or 30 minutes has elapsed. 2. Flow rate, as determined by PEAK FLOW and either the WAVEFORM or PRESSURE SLOPE does not exceed 20 LPM. (10 LPM for lower tidal volume).	1. Depress NEBULIZER key and ensure associated LED is lit. 2. Flow rate must exceed 20 LPM for nebulizer to operate. (10 LPM for lower tidal volume).
	RUN DIAGNOSTICS Alarm	1. Nebulizer solenoid fault.	1. Provide alternate source of gas delivery to nebulizer. Refer unit to an authorized service technician.
Patient cannot trigger an assisted breath or obtain gas from demand system.	Low TOTAL BREATH RATE Alarm	1. Inadequate ASSIST SENSITIVITY setting or Flow Trigger setting. 2. Patient circuit leak. 3. Worn or damaged exhalation valve diaphragm.	1. Re-evaluate patient and ASSIST SENSITIVITY or Flow Trigger setting. 2. Check patient circuit for leaks. 3. Perform leak test (Section 3), and replace diaphragm if it leaks or is damaged.
Pressure level for Pressure-Supported or Pressure-Controlled breaths is low for all or a portion of the breath.	Low PEAK INSP PRESSURE Alarm	1. PRESSURE SLOPE setting too low. As a result, flow rate is below patient demand. 2. PRESSURE SUPPORT or INSPIRATORY PRESSURE setting too low.	1. Re-evaluate patient and PRESSURE SLOPE setting. 2. Re-evaluate setting.